C. Remarks

The claims are 1 and 3-14, with claims 1 and 12 being in independent form. Claim 2 has been cancelled without prejudice or disclaimer of the subject matter disclosed therein. Claims 5-8 and 11-14 have been withdrawn from consideration. Claims 1 and 3-14 have been amended to make them consistent with the preliminary amendment of December 7, 2004 and to correct some formal errors. Claim 9 has also been amended for proper antecedent basis purposes. No new matter has been added. Favorable reconsideration is requested.

Claims 1-4 and 9 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over WO 01/12161 ("Martani") in view of S.T.P. Pharma Sciences 11 (3) 211-220, 2001 ("Mattsson"). The grounds of rejection are respectfully traversed.

Prior to addressing the merits of the rejection, Applicants would like to discuss some of the features and advantages of the presently claimed invention. That invention is related to a tablet for oral administration that disintegrates quickly in the oral cavity in less than 30 seconds, comprising i) spray-dried mannitol in a proportion of at least 59.5%; ii) active ingredient in a proportion below or equal to 10%, as a fine powder in which at least 90% in weight of the active ingredient has a particle size less than 100 μm; iii) microcrystalline cellulose in a proportion from 10 to 18%, with an average particle size of approximately 50 μm where at least 99% in weight of microcrystalline cellulose has a particle size below 250 μm; iv) sodium croscarmellose in a proportion from 1 to 4%; and v) a lubricant agent in a proportion from 0.5 to 2% in weight. The tablet has a friability below 0.5%.

The particle size of the active ingredient as recited in the claims plays a significant role in producing a tablet that is palatable. As mentioned in the specification at page 7,

lines 21-25, "to guarantee the palatability of the finished product and the uniformity of the mixture, the active ingredient must be a fine powder, where at least 90% in weight of the active ingredient has a particle size of below 100 μm." Similarly, the claimed microcrystalline cellulose particle size and its proportion in the tablet make it "possible to significantly improve compressibility, reduce friability and achieve a substantial reduction in disintegration time. Higher quantities have a negative impact on the palatability of the formula and lower quantities worsen the capacity of the disintegration promoter." (Page 8, lines 2-8).

Martani discloses a solid dosage form that rapidly disintegrates in an aqueous medium, which comprises an active substance, a filler selected from the group consisting of mannitol, lactose, calcium phosphates, dibasic calcium phosphates, microcrystalline cellulose, cyclodextrine, starch, laevulose, maltitol, polydextrose, sucrose, glucose, inulin, sorbitol or xylitol, and a disintegration agent selected from the group consisting of croscarmellose Na, agents based on sodium carboxymethyl cellulose and starch, sodium glycolates of starches, poly-N-vinyl-2-pyrrolidones, starches, polymethylmethacrylates, polysaccharides or synthetic resins. As acknowledged by the Examiner, Martani does not teach at least the claimed particle sizes of the active ingredient and microcrystalline cellulose and the friability value of the tablet. In fact, Martani's disclosure of 30% microcrystalline cellulose ("filler") teaches away from the present claims, which recite that the tablet contains 10-18% microcrystalline cellulose. See Martani, page 11, third full paragraph. In addition, Martani does not disclose or suggest the use of spray-dried mannitol.

Mattsson does not remedy the deficiencies of Martani. Mattsson discloses rapidly disintegrating tablets comprising a compound such as sodium chloride, a binder such as microcrystalline cellulose and a superdisintegrant such as carboxy methyl cellulose sodium. Mattson does not disclose or suggest spray-dried mannitol, microcrystalline cellulose with a particle size of approximately 50 μm or the friability value of the tablet.

The Examiner has not given the term "spray-dried" mannitol any patentable weight as it allegedly relates to a process and is not essential to the determination of patentability of the claimed composition. Applicant respectfully disagrees and notes that this form of mannitol is structurally different from other mannitol forms. The specification, at page 6, lines 19-22, states that "[s]pray-dried mannitol is made up fundamentally by the crystalline form α, unlike other types of mannitol, which are made up of the β form." In fact, the Examiner acknowledged the same on page 2 of the Office Action dated April 16, 2009. According to the product description from a manufacturer's website (submitted with the Information Disclosure Statement filed concurrently herewith), Pearlitol® mannitol powder is available in crystalline and granulated forms, i.e., mannitol is available in several different forms. Mattson teaches away from the present invention as it uses "granulated mannitol (250-425 μm, Roquette, France)". See Mattson, Section 1.1 on page 1.

Spray-dried mannitol helps to produce a tablet with a friability below 0.5% as evidenced from Tables IV and V of the present specification. As shown in these tables, the friability of the tablet is outside the claimed range of below 0.5% (see Example 5) when direct compression dextrose is used in the place of spray-dried mannitol of the other Examples in these tables.

In addition, neither Martani nor Mattson recognizes the importance of the particle size of the active ingredient. According to the Examiner, the disclosure in Table I of Mattson of "90-180" μm DCP satisfies the claimed particle size requirement of the active ingredient. However, clearly there is no recognition of the importance of the particle size being less than 100 μm or disclosure as to what proportion of the particles in Mattson are between 90 and 100 μm. In fact, a predominant amount of the particles may be closer to 180 μm than to 100 μm. As discussed above, the particle sizes and their proportion as claimed provide the tablet with advantages properties. It is clear that these parameters are not the result of routine optimization.

Applicant has shown that the ingredients and their proportions as claimed are not the same as those in the cited references. Therefore, the Examiner's presumption that the prior art tablet would be expected to have the same friability values cannot be maintained.

Wherefore, Applicant respectfully submits that none of the references of record, whether taken alone or together, describes or suggests the presently claimed invention. Accordingly, it is respectfully requested that the claims be allowed and are passed to issue.

In view of the foregoing amendments and remarks, Applicant respectfully requests favorable reconsideration and early passage to issue of the present application. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicant's undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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